08/459,141

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/459,141	06/02/95	BERMAN	P P0233C6

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EXAMINER	
SMITH,L	
ART UNIT	**PAPER NUMBER**
1813	11

DATE MAILED: 04/23/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/10/97.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 sheets

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

* U.S. GPO: 1996-410-238/40050

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The examiner acknowledges the amendment filed 2/10/97 along with the declarations.

3. In view of applicants' remarks, declarations submitted and amendments to the claims, the following rejections are being withdrawn:

a) the rejection of claims under 35 U.S.C. 112 second paragraph as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

b) the provisional rejection of claims 10-23 under 35 U.S.C. 101 as claiming the same invention as that of copending application serial numbers 08/470,107 and 08/459,147

c) the rejections of claims under 35 U.S.C. 103

Applicant's arguments filed 2/10/97 have been fully considered but they are not deemed to be persuasive.

4. The rejection of claims 10, 11, 14-23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, 13, 14, 17, 20-23 of copending application serial number 08/357,084 is maintained essentially for reasons set forth in paper no.8, paragraph 8 of the previous office action. The examiner notes applicants' response to this ground of rejection.

5. The rejection of claims 10, 12, 13-17, 20-23 under 35 U.S.C. 112 first paragraph as the disclosure is only enabling for claims limited to a method of producing a glycoprotein D vaccine and a vaccine containing the glycoprotein D of herpes simplex virus is maintained essentially for reasons set forth in paper no. 8, paragraph 9 of the previous office action. The rejection was on the grounds that the specification was no-enabling for the full scope of the claimed subject matter.

Applicants' urges that challenge data was necessary in the Watson et al and the Rose et al publications because there was doubt as to whether the peptides would be effective against a challenge, that applicants' have demonstrated at least one successful challenge in accordance with the present invention and that without the challenge data it would not have been obvious to one of skill in the art that the vaccines would be successful, that applicants have shown comparisons of glycoprotein C and F, and the declarations submitted have provided evidence of the enablement of the present invention.

It is the examiner's position that the instant specification, as has already been previously stated, provides description and enablement for a vaccine containing glycoprotein D and a method of making the glycoprotein. Applicant has expressed the glycoprotein C, but did not administer the glycoprotein (either alone or in combination with other glycoproteins) to animals and subsequently challenge animals to show that the glycoprotein C and/or the mixtures of B, C and D were protective against HSV-1 and HSV-2 infections. The recitation

that it is believed that other combinations could be used does not provide enablement for a mixture as claimed.

It appears that the declaration have argued that it is not only necessary to show that a glycoprotein can be prepared or that a glycoprotein can raise neutralizing antibodies but that it must be protective (see Declaration of Dr. Rose). This protection was not shown for glycoprotein c or B or any combination of glycoproteins. Indeed the declarations support the production of a single truncated glycoprotein D and a vaccine containing the glycoprotein D. There is no description or enablement in any declaration for a glycoprotein B or C or a mixture of glycoproteins. It should be noted that in the EPO discussion Document, page 7, it was stated that while two reference disclose natural secretion of gD and gC fragments in culture medium, the immunogenicity activity was not tested. In the instant specification, while the gC glycoprotein was mentioned and expresses in a recombinant system, its immunogenicity was also not tested. Therefore, the declarations and applicants' remarks are not sufficient to enable the full scope of the claimed subject matter.

New Grounds of Rejection

6. Claims 10-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-23 of copending application Serial No. 08/470,107 and over claims 10-23 of copending application serial number 08/459,147. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the claims are drawn to membrane free derivatives of glycoproteins from herpes simplex, vaccines and method of producing the vaccines.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. The examiner is in the process of locating and re-ordering those publications listed on the PTO Form 1449 which were not crossed out. Those references which were crossed out were not considered because they were not present in the parent applications.

8. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Lynette F. Smith, Art Unit 1813 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1813 FAX telephone number is (703)-305-7939. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by

the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lynette F. Smith whose telephone number is (703) 308-3909.

Should the examiner be unavailable, Supervisory Patent Examiner Don Adams, Ph.D., may be reached on (703) 308-0570.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SMITH/lfs
April 17, 1997

L. F. Smith
LYNETTE F. SMITH
PRIMARY EXAMINER
GROUP 1800